

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number** 21-241

**PHARMACOLOGY REVIEW(S)**

REVIEW AND EVALUATION OF PHARMACOLOGY/TOXICOLOGY DATA:

KEY WORDS: norgestimate; ethinyl estradiol

Reviewer Name: Alex Jordan

Division Name: DRUDP

HFD#: 580

Review Completion Date: 2/28/01

Review number: 1

IND/NDA number: NDA 21-241

Serial number/date/type of submission: 00

Information to sponsor: Yes ( ) No (x)

Sponsor (or agent): R.W. Johnson Pharm Res Inst

Manufacturer for drug substance:

**APPEARS THIS WAY  
ON ORIGINAL**

Drug:

Code Name:

Generic Name: norgestimate/ethinyl estradiol

Trade Name:                     

Chemical Name:

CAS Registry Number:

Molecular Formula/ Molecular Weight:

Structure:

Relevant INDs/NDAs/DMFs: IND's 11,391; 50,488

Drug Class: contraceptive steroids

Indication: contraception

Clinical formulation:

Route of administration: oral

OVERALL SUMMARY AND EVALUATION:

Introduction:                      is comprised of norgestimate and ethinyl estradiol, both approved drugs in NDA's 19-653 and 19-697. This NDA is for a lower dose estrogen.

Safety Evaluation: There are no safety issues

Labeling review (NDA): The label is acceptable

RECOMMENDATIONS: Approval of NDA 21-241

**APPEARS THIS WAY  
ON ORIGINAL**

/s/

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Alexander W. Jordan  
3/27/01 11:25:42 AM  
PHARMACOLOGIST

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**APPEARS THIS WAY  
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(E)

**Number of Pages**  
**Redacted** 35



Draft Labeling  
(not releasable)

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